UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,841	02/15/2005	Naoyuki Taniguchi	47234-0003	7031

55694 7590 07/11/2008

DRINKER BIDDLE & REATH (DC)
1500 K STREET, N.W.
SUITE 1100
WASHINGTON, DC 20005-1209

EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
07/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,841	TANIGUCHI ET AL.	
	Examiner	Art Unit	
	IQBAL H. CHOWDHURY	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/8/08; 10/31/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7 and 23-30* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☒ Claim(s) *6,25-27 and 29* is/are allowed.

6)☒ Claim(s) *7,24, 28, 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

Claims 1, 4-7 and 23-24 are pending in the instant Office action.

Applicant's election with traverse of SEQ ID NO: 7 in a supplemental Restriction Requirement in the communication filed on 4/8/2008 is acknowledged.

Applicant's traverse is on the ground(s) that the SEQ ID NO: 7 and 11 overlap each other, i.e. SEQ ID NO: 11 is an obvious variant of SEQ ID NO: 7. Therefore, the restriction requirement is withdrawn and SEQ ID NO: 7 and 11 will be examined on the merits.

In response to a previous Office action, a Final action (mailed on April 11, 2007), Applicants have filed an amendment on October 31, 2007, amending claims 6-7 and 23-24, canceling claims 1 and 4, and adding new claims 25-30 is acknowledged. Claim 23 remain withdrawn as drawn to non-elected invention, and claims 2-3, and 8-22 remain cancelled.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

Claims 6-7 and 24-30 are under consideration and will be examined herein.

Applicants' arguments filed on October 31, 2007 have been fully considered but are not deemed persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

New Claim objections

Claim 24 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 7 because said agent, which is a product that comprises same polypeptide irrespective of the intended use recited in the preamble. M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Appropriate correction is required.

New-Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 28 is indefinite and vague in the recitation of "consisting of the amino acid sequence shown in SEQ ID NO: 11", which is confusing because it is impossible for a polypeptide of claim 25 to be "consisting of the amino acid sequence shown in SEQ ID NO: 11" (i.e., a 6 amino acid long peptide) and "comprising the amino acid sequence of SEQ ID NO: 7 (i.e., a 17 amino acid long peptide) at the same time. "Consisting of" excludes the presence of

additional amino acids while in order for the peptide to comprise SEQ ID NO:7 (as required by claim 25, from which claims 28 depends, at least 11 additional amino acids must be present.

Claims 7, 24, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7, 24, and 30 are indefinite and vague in the recitation of the "pharmaceutically effective amount" which is confusing. It is not clear to the Examiner the term "effective" for what? The specification does not teach what the amount should be effective for.

New-Claim Rejections - 35 USC § 112, First Paragraph (New matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 24 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 7, 24 and 30 are directed to a wound healing agent or an agent for treating atherosclerosis comprising a pharmaceutically effective amount of a polypeptide fragment and pharmaceutically acceptable carrier therefor. The specification does not teach "pharmaceutically effective amount", which constitutes a new matter.

There is no indication in the specification to recite pharmaceutically effective amount" as recited in the claims, which were within the scope of the invention as conceived by Applicants at the time the application was filed. Accordingly, Applicants are required to cancel the new matter in response to this Office Action.

Withdrawn-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Previous rejection of Claim 5 under 35 U.S.C. 102(b) as being anticipated by Taniguchi et al. (US Patent 5,834,284, publication 11/10/1998, see IDS) is withdrawn in view of cancellation of claim 5.

Previous rejection of Claims 1, 4-7 and 24 under 35 U.S.C. 102(b) as being anticipated by Nakahara et al. (US Patent 6,191,113 B1, 2/20/2001) is withdrawn in view of applicants new claim 25 and amendment of claims 6-7. Indeed Nakahara et al. do not teach a polypeptide fragment of N-acetylglucosaminyltransferase V (GnT-V) comprising a basic cluster region that comprises the amino acid sequence of SEQ ID NO: 7 and up to 50 contiguous amino acids encoded by SEQ ID NO: 6.

Previous rejection of Claims 1, 4-7 and 24 under 35 U.S.C. 102(b) as being anticipated by Selwood et al. (WO 02/34767 A1, publication 5/2/2002) is withdrawn in view of applicants new claim 25 and amendment of claims 6-7. Indeed Selwood et al. do not teach a polypeptide fragment of N-acetylglucosaminyltransferase V (GnT-V) comprising a basic cluster region that

comprises the amino acid sequence of SEQ ID NO: 7 and up to 50 contiguous amino acids encoded by SEQ ID NO: 6.

Previous rejection of Claims 1, 4-7 and 24 under 35 U.S.C. 102(b) as being anticipated by Tischer et al. (J Biol Chem. 1991 Jun 25; 266(18): 11947-54) is withdrawn in view of applicants new claim 25 and amendment of claims 6-7. Indeed Tischer et al. do not teach a polypeptide fragment of N-acetylglucosaminyltransferase V (GnT-V) comprising a basic cluster region that comprises the amino acid sequence of SEQ ID NO: 7 and up to 50 contiguous amino acids encoded by SEQ ID NO: 6.

Conclusion

Claims 25, 6-7, 24 and 26-30 are pending.

Claim 23 is withdrawn.

Claims 7, 24, 28 and 30 are rejected.

Claims 25, 6, 26-27 and 29 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, PhD Patent Examiner
Art Unit 1652 (Recombinant Enzymes)
US Patent and Trademark Office
Remsen Bldg., Rm. 2B69, Mail Box. 2C70
Ph. (571)-272-8137, Fax. (571)-273-8137

/I. H. C./
Examiner, Art Unit 1652

/Rebecca E. Prouty/
Primary Examiner,
Art Unit 1652